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ARTICLE

CIRCLES: CLOSING THE EVIDENCE GAP IN ROBOTIC-ASSISTED TOTAL KNEE ARTHROPLASTY

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Total Knee Arthroplasty (TKA) is a life-changing intervention for patients with end-stage knee osteoarthritis. With over 600,000 procedures performed annually in the U.S. — and projected to rise nearly sevenfold by 2030 — its impact is profound. Yet, despite the success of conventional techniques, up to a quarter of patients remain dissatisfied, often due to the inability to fully replicate the natural motion of the knee.

The emergence of Robotic-Assisted TKA (RA-TKA) promises unprecedented precision in implant placement and alignment, with the aim of improving patient satisfaction and long-term implant survivorship. But the technology's adoption is slowed by unresolved debates, inconsistent outcomes data, and the high financial burden of robotic systems.

The orthopedic community continues to grapple with critical questions:

- Does RA-TKA truly deliver superior patient-perceived benefits in the long term?
- Is kinematic alignment (KA) better than mechanical alignment (MA)?
- Can the costs and learning curve be justified by measurable improvements in outcomes?

Randomized Controlled Trials (RCTs) are the gold standard for evaluating surgical interventions, but they have limitations in real-world applicability due to controlled environments and narrow patient selection. Real-World Evidence (RWE) fills this gap, capturing data from routine clinical practice.

However, traditional "big data" RWE sources — derived from EMRs, registries, and insurance claims — are often incomplete, unverifiable, and lack the longitudinal follow-up needed for meaningful conclusions. These shortcomings hinder the ability to answer pressing RA-TKA questions, particularly around alignment strategies, implant longevity, and cost-effectiveness.

RegenMed's Circles platform is engineered to address these evidence gaps with a methodology that mirrors the rigor of clinical trials while maintaining the practicality of real-world data collection.

KEY FEATURES:

- **Direct, Verifiable Data Sourcing:** Information comes straight from physicians, patients, and laboratories, each datapoint time-stamped and immutable.
- **Longitudinal Case Tracking:** Every dataset follows a complete patient journey, from enrollment through long-term outcomes, capturing critical measures like implant survivorship and patient satisfaction.
- **Protocol-Driven Relevance:** Each dataset is tied to a specific Observational Protocol (OP) for targeted, clinically meaningful insights — such as robotic KA vs. MA comparisons.
- **Good Clinical Practice (GCP) Compliance:** The platform inherently supports ethical and regulatory standards, including IRB processes and patient consent.
- **Equitable Ownership and Benefits:** Circle members retain data ownership and can receive up to 85% of licensing value, incentivizing participation.

SOLVING RA-TKA'S EVIDENCE CHALLENGES:

- **Quality and Verifiability:** Circles eliminates the ambiguity of traditional datasets, enabling robust comparative studies of alignment strategies and robotic platforms.
- **Long-Term Outcomes:** Continuous data capture supports proactive monitoring of implant performance, complications, and evolving patient satisfaction.
- **Cost-Effectiveness:** Granular, structured data allows detailed economic analyses, critical in evaluating the true return on investment of robotic systems.
- **Surgeon Learning Curve:** Performance tracking over time can inform training programs and credentialing standards.
- **Patient-Reported Outcomes (PROMs):** High-fidelity capture ensures the patient's voice is central in assessing surgical success.

CONCLUSION

Robotic-assisted knee replacement holds tremendous promise, but the orthopedic field needs better answers before widespread adoption. Circles provides the framework to generate those answers — efficiently, cost-effectively, and with clinical rigor. By combining the precision of RA-TKA with the precision of high-quality RWE, Circles can guide technology adoption, resolve long-standing debates, and improve patient outcomes at scale.

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